

REMARKS

An Office Action was mailed in the above-captioned application on August 3, 2010. Claims 1-4 and 8-20 were pending. Claims 5-7 were previously withdrawn. Claim 2 has been canceled and incorporated into Claim 1. Claims 1, 3, 4, 8, 9, 11-14 and 16-18 have been amended in this response. Support for the claim amendments may be found throughout the specification and specifically in the abstract, p. 10 lines 17-18 and in the Examples section. In addition, the specification has been amended to correct a typographical error. No new matter is believed to have been added by the amendments. This Amendment and Remarks document is submitted in response to said Office Action.

Election:

The Examiner has acknowledged the Applicant's election with traverse of Group I and has indicated that the requirement is deemed proper and is therefore made final.

Objection:

The Examiner has objected to Claim 1 for lacking a period. Claim 1 has been amended to include a period and withdrawal of this objection is requested.

Rejection Under 35 U.S.C. § 112-Enablement:

The Examiner has rejected Claims 1-4 and 8-20 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner asserts that the specification while being enabling for embodiments of the claimed method where the solid fat is used as a solvent for the one or more active ingredients, does not reasonably provide enablement for the scope of Claim 1, that is, to a method of preparing nanoscale or amorphous particles using any ratio of one or more active ingredients to solid fat. The Examiner concludes that the specification does not enable one of skill in the art, to prepare nanoscale or amorphous particles according to the method of claim 1 using any ratio of one or more active ingredients to solid fat, commensurate in scope with the claims.

Applicant's respectfully disagree with the Examiner's assertions, however in order to expedite prosecution, Claims 1 and 4, for which claims 3, 8-20 depend upon, have been amended to include the solid fat as a solvent in an excess amount to the active ingredient. In view of this

amendment, Applicants submit that there is adequate enablement in the specification for Claims 1-3 and 8-20 as amended and request the Examiner's rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection Under 35 U.S.C. § 112-Indefinite

The Examiner has rejected Claim 14 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner asserts that Claim 14 is indefinite because (1) it is unclear how there can be a co-solvent in Claim 1 as there is no first solvent in Claim 1 and (2) because it is unclear in what way the co-solvent is further used in step (1).

Claim 14 has been amended to clarify that the mixture prepared in step (1) of claims 1 or 4 further comprises a co-solvent. In view of this amendment, Applicants submit that amended Claim 14 is not indefinite and therefore requests the Examiner's rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejection Under 35 U.S.C. § 102

The Examiner has rejected Claims 1, 8-11 and 14-18 under 35 U.S.C. § 102(a) and (e) as being anticipated by US 20040043076 (herein referred to as '076). In accordance with MPEP 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The Examiner asserts that '076 discloses a method for preparing amorphous particles comprising bringing a particulate active ingredient and a coating agent, such as solid fatty esters (a solid fat), into contact with stirring, in supercritical CO₂, adjusting the temperature and pressure of the supercritical CO₂ to deposit the coating agent onto the particulate active ingredient, and subsequently removing the supercritical fluid. The Examiner does note that '076 does not teach the excess solid fatty acid ester in supercritical fluid, owing to the solubility of the solid fatty acid ester in supercritical CO₂, however, the Examiner asserts that it is reasonable that excess solid fatty acid ester would be extracted from the active ingredient.

Applicants have amended Claims 1 and 4 for which claims 8-11 and 14-18 depend upon. In addition, '076 relates to a method for coating particles of an active ingredient with a lipid as a

coating agent wherein the lipid is dissolved in a supercritical fluid (SCF) and used during the coating procedure, without using an organic solvent. In '076, the particles of the active ingredient to be coated were already made prior to the coating procedure and during the procedure. '076 does not use a lipid as a solvent to the active ingredient as claimed. In '076, a lipid is initially used as a solute to be dissolved in SCF and then precipitated and adsorbed on the surface of the active ingredient particles by adjusting temperature and pressure. No procedure to remove the lipid is involved in the '076 method. Specially, '076 teaches that particles of an active ingredient are suspended in SCF; the temperature and pressure are slowly raised to dissolve the lipid as a coating agent completely in the SCF; the temperature and pressure are then lowered to precipitate the coating agent and form its coating on the surface of the active ingredient particles, then the SCF is removed. No procedure to remove the residual lipid is disclosed in '076.

As '076 does not teach or suggest all of the elements of independent Claims 1 or 4, for which claims 8-11 and 14-18 depend upon, Applicants respectfully request the Examiner's rejection under 35 U.S.C. § 102(a) and (e) be withdrawn.

Rejection Under 35 U.S.C. § 103:

The Examiner has rejected Claims 1, 8-11 and 14-18 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent. No. 6,471,993 (herein referred to as '993), in view of U.S. Patent Publication No. 20060035350 (herein referred to as '350). The Examiner bears the burden of establishing a *prima facie* case of obviousness (Section 103). In determining obviousness, one must focus on Applicant's invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1991). Accepted rationales for obviousness include a combination of prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; use of known technique to improve similar products in the same way; or applying a known technique to a known product ready for improvement to yield predictable results. *KSR v. Teleflex*, 550 U.S. 398, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007).

Specifically, the Examiner asserts that it would have been obvious to use supercritical carbon dioxide to extract triglyceride porogens in the method of '993 because '993 teaches that supercritical carbon dioxide is a common solvent for triglycerides thus teaching equivalency of

other solvents specifically used by '993. The resulting method would be a method comprising the steps of (1) preparing a mixture comprising one or more active ingredients and solid fat and (2) pressurizing the mixture comprising one or more active ingredients and solid fat to the critical pressure or more by adding the gas of a supercritical fluid into the mixture, and then removing the solid fat from the mixture by releasing out the solid fat together with the gas of a supercritical fluid. The Examiner further asserts that it would have been further obvious to optimize the temperature and pressure of the extraction process as temperature and pressure are routinely optimized parameters when using and maintaining supercritical fluids.

Applicants have amended Claims 1 and 4 for which claims 8-11 and 14-18 depend upon. In addition, '993 and '350 both relate to a method for forming many voids in a polymer. In both references, a polymer is dissolved in a suitable solvent and lipid particles such as a porogen are uniformly dispersed in the polymer solution. The particles are then removed by dissolving them in a solvent which can do so. Neither '933 nor '350 alone or in combination teach or suggest solid fat (lipid) used as a solvent as claimed.

In view of the claim amendments and comments above, Applicants contend that Claims 1, 8-11 and 14-18 are not obvious in view of '993 and '350 and respectfully request withdrawal of this rejection.

Closing Remarks

If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time or excess claim fees and an authorization to charge all fees therefore to deposit account No. 19-1970, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

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